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In The

Supreme Court of the United States

ALBERTSON'S, INC., et al.,

Petitioners,

v.

JENNIFER KANTER, et al.,

Respondents.

On Petition For A Writ Of Certiorari To The California Supreme Court

BRIEF OF REXALL SUNDOWN, INC., AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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INTRODUCTION AND INTEREST OF *AMICUS CURIAE*

Amicus curiae Rexall Sundown, Inc. ("Rexall Sundown") respectfully submits this brief in support of petitioners Albertson's, Inc., The Kroger Co., Safeway, Inc., and Bristol Farms, Inc.[1]

Rexall Sundown is a leader in the health products industry. It develops, manufactures, markets, and sells a broad line of vitamins, herbals, and nutritional supplements under various brand names. Rexall Sundown's products are sold in a variety of retail outlets throughout the United States, including mass merchandisers, drugstore chains, supermarkets, independent drugstores, and health food stores. Rexall Sundown's products are subject to labeling requirements established by the federal Food, Drug and, Cosmetic Act (FDCA), 21 U.S.C. § 301 (2008), et seq., and implementing regulations issued by the Food and Drug Administration (FDA).

Rexall Sundown is a defendant in a pending private California state court action entitled *Jarvis, et al. v. Royal Numico N.V., et al.,* California Superior

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[1] This brief is submitted with the written consent of counsel for all parties, who were timely notified pursuant to United States Supreme Court Rule 37.2(a) of the intention of *amicus* to file this brief. The brief was authored solely by *amicus* and its counsel. It was not authored in whole or in part by counsel for any party. No one other than *amicus* made any monetary contribution to the preparation or submission of this brief.

Court Case No. CGC-02-403532 ("*Jarvis*").[2] The complaint alleges that Rexall Sundown engaged in unfair competition in violation of California law by selling nutrition products bearing labels making various claims about the carbohydrate content of the products – for example, that the products are low in carbohydrates or "low carb" – that purportedly are unlawful under both the FDCA and California's state-law equivalent, or "little FDCA," the Sherman Food, Drug, and Cosmetic Law (Sherman Law), Cal. Health & Safety Code § 109875 et seq., which incorporates the provisions of the FDCA and its implementing regulations.

Rexall Sundown has asserted as a defense in *Jarvis* that the FDCA preempts the plaintiffs' claims. In the petitioners' case ("the *Farm Raised Salmon* case"), the California Supreme Court recognized that private state law actions, like *Jarvis*, seeking to enforce the FDCA conflict with the Congressional plan to vest FDCA enforcement exclusively with the FDA (and, in certain limited circumstances, with state governments as well). Therefore, the California Supreme Court acknowledged that the FDCA pre-empts such private FDCA enforcement actions. *See*

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[2] The other defendants in *Jarvis* are Rexall Sundown subsidiaries (Richardson Labs, Inc., MET-Rx USA, Inc., and Worldwide Sport Nutritional Supplements, Inc.), a former parent of Rexall Sundown (Royal Numico N.V.), a former Rexall Sundown sister company and retailer of Rexall Sundown products (General Nutrition Corporation), and a Rexall Sundown brand name (Low Glycemic Technologies, Inc.).

Pet. App. 11, 31-33. The California Supreme Court, however, also held that the FDCA does not bar similar private actions predicated on state laws like California's Sherman Law, which impose requirements identical to the FDCA. Pet. App. 3.

If the California Supreme Court's decision stands, it could impair Rexall Sundown's federal preemption defense to the claims asserted against it in the *Jarvis* matter based on alleged violations of California's Sherman Law. The *Jarvis* action, in fact, was stayed pending the California Supreme Court's decision in the *Farm Raised Salmon* case. Accordingly, the *Farm Raised Salmon* decision has a direct bearing on Rexall Sundown's interests.

The *Jarvis* case demonstrates how private "little FDCA" enforcement actions will impede the FDA's authority to make regulatory decisions based on the latest scientific knowledge available, and instead will leave such decisions to the whim of private litigants and their attorneys to determine when, who, and for what to sue without regard to the FDA's judgment. Although the FDA in the past has sent warning letters to Rexall Sundown subsidiaries and other companies raising objections to the use of terms such as "low carb," the FDA has since recognized that such carbohydrate content claims may be not only appropriate but also beneficial to consumers in light of recent scientific advances in the area of nutrition. For this reason, the FDA has announced that it will consider promulgating new regulations that will allow such carbohydrate content claims to appear on

food labels. In the interim, the FDA has exercised its discretion not to take any formal enforcement action against companies like Rexall Sundown that have used such terms to describe their products.

Permitting individuals to bring private actions alleging that carbohydrate content claims violate the requirements of state laws like California's Sherman Law, which are identical to the FDCA and its implementing regulations as they currently stand, will directly undermine the FDA's considered judgment concerning the propriety of carbohydrate content claims and how best to address them. More broadly, such private enforcement actions will subvert the federal policy to ensure that the FDA, and only the FDA, with its specialized knowledge and expertise, makes decisions based on the most current scientific developments about what nutritional information should be provided on food labels to best guide consumers.

The FDA's reconsideration of the propriety of carbohydrate content claims is not unique. Given developments in scientific knowledge about nutrition, the FDA frequently is required to reevaluate its regulations, or at least make informed decisions about when and how to enforce them, to best serve the overriding federal objectives to make available to consumers consistent nutrition information that can assist them in making healthier food choices, while at the same time "encourag[ing] product innovation through the development and marketing of nutritionally improved foods." Food Labeling: Nutrient

Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302, 2302 (Jan. 6, 1993). While the FDA has the ability to ensure that *state governments* interpret, apply and enforce their state counterparts to the FDCA consistently with the FDA's decisions, the FDA has no such control over private parties and their attorneys. Therefore, and contrary to the decision of the California Supreme Court, private actions seeking to enforce state duplicates of the FDCA conflict with the FDA's regulatory mandate and should be precluded under the doctrine of conflict preemption, just as such actions are preempted when they attempt to enforce the FDCA itself.

It is for the FDA, not private litigants, to interpret FDCA regulations and decide when and how to apply them in light of the FDA's expertise in the areas it regulates. The California Supreme Court's decision allows private parties, who, unlike the FDA, do not represent the public interest, to usurp the FDA's authority so long as they do so pursuant to state duplicates of the FDCA and not the FDCA itself. But the California Supreme Court's distinction between allowing private parties to enforce the FDCA and allowing them to enforce its state-law duplicates is one without a difference. The interference with the FDA's ability to regulate consistently and appropriately in the field committed to its discretion is the same.

For these reasons, Rexall Sundown urges this Court to review and reverse the decision of the California Supreme Court in the *Farm Raised Salmon* case.

ARGUMENT

PRIVATE "LITTLE FDCA" ENFORCEMENT ACTIONS WILL USURP THE FDA'S EXCLUSIVE AUTHORITY TO REGULATE UNIFORMLY, AS ILLUSTRATED BY THE *JARVIS* CASE.

Because the *Jarvis* case provides a prime example of how private actions to enforce state counterparts of the FDCA will obstruct the FDA's regulatory authority, it is important to understand the details of the *Jarvis* case as well as the relevant regulatory framework established by the FDA. Accordingly, in the first section below, we outline the allegations of the *Jarvis* complaint. In the following two sections, we set forth the current applicable FDCA regulations, and the FDA's position on the enforcement of those regulations while the FDA reconsiders them in the face of advances in nutritional science. Finally, in the last section of this brief, we demonstrate that private "little FDCA" enforcement actions like *Jarvis* will compromise the FDA's regulatory decisions and interfere with its congressional mandate to ensure uniformity in food labeling in a manner that provides consumers with consistent and valuable nutrition information, but also encourages industry to develop

and market nutritional products that will appeal to the consuming public. *See* 58 Fed. Reg. at 2302.

A. The *Jarvis* Complaint Alleges That *Amicus* Rexall Sundown Violated California's Unfair Competition Law Because Its Product Labels Include Carbohydrate Content Claims That Allegedly Are Impermissible Under Both The FDCA And California's "Little FDCA," The Sherman Law.

The plaintiffs in *Jarvis* assert that *amicus* Rexall Sundown engaged in unfair competition in violation of California law, Bus. & Prof. Code § 17200, et seq., by marketing, distributing, and selling nutrition products – including bars, cookies, powders, and ready-to-drink mixes – whose packaging and labels state they are "Low Carb" or appropriate "For Low Carb Diets," signifying that the products are low in carbohydrates. The *Jarvis* plaintiffs also allege that Rexall Sundown improperly excluded from the "total carbohydrate" entry on the nutrition facts panel of its product labels ingredients, such as fiber, that do not have a significant impact on blood-sugar levels, and therefore typically do not count in low-carbohydrate diets. And the *Jarvis* plaintiffs allege that Rexall Sundown product labels improperly used the term "net carbs," which signifies the amount of carbohydrates of the type that impact blood-sugar levels, subtracting out ingredients that do not.

The *Jarvis* complaint alleges as a predicate to the unfair competition cause of action that these

carbohydrate content claims are not authorized by the FDCA or its implementing regulations, and therefore also violate California's Sherman Law, which provides that "[a]ll food labeling regulations and any amendments to those regulations adopted pursuant to the [FDCA] . . . shall be the food labeling regulations of this state." Cal. Health & Safety Code § 110100(a).

The *Jarvis* plaintiffs seek, among other things, a preliminary and permanent injunction prohibiting Rexall Sundown from continuing to make such allegedly improper carbohydrate content claims on its product labels, disgorgement of all funds Rexall Sundown acquired through the sale of products whose labels included the allegedly improper carbohydrate content claims, and attorneys' fees.

B. The FDCA And Its Implementing Regulations (And Therefore The Sherman Law) Presently Do Not Establish Definitions For Terms Such As "Low Carb" And "Net Carb."

In November 1990, the Nutrition Labeling and Education Act (NLEA) was signed into law, amending the FDCA. As the FDA has recognized, "the 1990 amendments [to the FDCA] ha[d] three basic objectives. . . . : (1) To make available nutrition information that can assist consumers in selecting foods that can lead to healthier diets, (2) to eliminate consumer confusion by establishing definitions for nutrient content claims that are consistent with the terms

defined by [the FDA], and (3) to encourage product innovation through the development and marketing of nutritionally improved foods." 58 Fed. Reg. at 2302.

The FDCA, as amended by the NLEA, requires that all foods intended for human consumption (with limited exceptions not applicable here) bear labels indicating the amount of specified nutrients contained in the food, including the "total carbohydrates." 21 U.S.C. § 343(q)(1)(D) (2008). FDA regulations promulgated pursuant to the NLEA provide that "[t]otal carbohydrate content shall be calculated by subtraction of the sum of the crude protein, total fat, moisture, and ash from the total weight of the food." *See* 21 C.F.R. 101.9(c)(6) (2008). As such, the FDCA and its implementing regulations (and therefore the Sherman Law as well) presently do not expressly provide for the exclusion of ingredients that do not have a significant impact on blood-sugar levels from the "total carbohydrate" designation on food labels, even though due to their physiological impact the carbohydrates derived from these ingredients generally are irrelevant to carbohydrate-conscious consumers.

The FDCA, as amended by the NLEA, also provides that a food intended for human consumption is misbranded if it makes a claim on its label that expressly or implicitly characterizes the level of any nutrient required to be declared on the labeling (including carbohydrates), unless the claim uses a term that is defined in regulations promulgated by the FDA. 21 U.S.C. § 343(r)(1)(A), (2)(A) (2008).

To implement this portion of the NLEA, in 1993 the FDA published regulations that define and establish criteria for use of various descriptors, such as "free" and "low," for specified nutrients. *See* 58 Fed. Reg. at 2302; *see also, e.g.*, 21 C.F.R. 101.60(c)(1) (2008) (defining "sugar free"); 21 C.F.R. 101.62(b)(2) (2008) (defining "low fat"). At the time, however, the FDA did not define these terms for carbohydrates. *See* 58 Fed. Reg. at 2343. The FDA reasoned that "claims for specific amounts of carbohydrates . . . [cannot] be supported based on dietary recommendations in the major consensus reports because quantitative recommendations for carbohydrate consumption are not included." Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 60421, 60453 (Nov. 27, 1991). Beyond that, the FDA had little reason to address carbohydrate content claims because, at the time of its rulemaking, consumer interest in carbohydrates was relatively low and such claims were rarely made on product labels.

C. The FDA Has Announced That It Will Reconsider Its Position On Carbohydrate Content Claims In Response To Recent Scientific Developments, And It Has Exercised Its Discretion In The Meantime Not To Take Formal Enforcement Actions With Respect To Such Claims.

Circumstances have changed dramatically since the FDA in 1993 determined how "total carbohydrate"

should be calculated and declined to define terms such as "low" with respect to carbohydrates. In the ensuing years, nutritional science has developed at a tremendous pace, challenging conventional diet wisdom. More definitive recommendations on carbohydrates have emerged, consumer interest in low-carbohydrate diets has surged while an obesity epidemic has swept the country, and carbohydrate-conscious products have been developed and marketed at a dizzying pace in response to escalating consumer demand. *See generally* Andrew Cooper, *Carbohydrate Nutrient Content Claims: Proposals for FDA Action and Lessons for Regulatory Response to Emerging Consumer Trends* (April 2006), at 1, 29, available at http://leda.law.harvard.edu/leda/data/763/Cooper06.pdf. The FDA has noted these developments and has responded accordingly.

On March 12, 2004, the FDA released a report by its Obesity Working Group, outlining the FDA's strategy to combat obesity in the United States. Among other things, the report recommended that the FDA implement uniform rules for carbohydrate labeling, including establishing an approved definition of "low carbohydrate" and providing guidance regarding "net carbohydrate" statements on product labels. *See* FDA OBESITY WORKING GROUP, CALORIES COUNT: REPORT OF THE WORKING GROUP ON OBESITY (2004), available at http://www.cfsan.fda.gov/~dms/owg-toc.html.

On the same day, the FDA published a Fact Sheet on Carbohydrates, which recognized that "in

response to consumer interest in popular low carbohydrate diets," many processed food manufacturers are making claims such as "low," "reduced," or "free" to describe the amount of carbohydrate in their products. *See FDA Fact Sheet on Carbohydrates* (Mar. 12, 2004), available at http://www.fda.gov/oc/initiatives/obesity/factsheet.html. The FDA noted that "[t]hese claims are nutrient content claims (i.e., they characterize the amount of a nutrient, carbohydrate, in a food) and must be made in accordance with an authorizing regulation," but that "[c]urrently, FDA's regulations do not define any term to describe the amount of carbohydrate in a food." *Id.* The FDA stated that it "intends to initiate rulemaking proceedings for nutrient content claims for carbohydrate. In addition, the agency intends to provide guidance to food manufacturers on the use of the term 'net' in relation to the carbohydrate content of food." *Id.*

In August 2004, Lester Crawford, the FDA's Acting Commissioner, reiterated that the FDA plans to "demystify carbohydrates" by "publishing a proposed rule and providing guidance regarding claims on the carbohydrate content of foods," including the use of terms such as "low carb" and "net carb." *See* Newsmaker Luncheon Speech by Lester M. Crawford, Acting Commissioner of the FDA (Aug. 2, 2004), available at http://www.fda.gov/oc/speeches/2004/newsmaker0802.html.

As promised, the FDA accepted and opened dockets during 2004 for several citizens' petitions (by both industry and consumer groups) which requested

the FDA to promulgate rules and guidelines regarding carbohydrate labeling, including claims such as "carbohydrate free," "low carbohydrate," "reduced carbohydrate," and "net carbohydrate." *See* FDA Docket Nos. 2204p-0105, 2004p-0107, 2004p-0110, 2004p-0297, 2004p-0298, 2004p-0299, 2004p-0473, and 2004p-0542, available at http://www.fda.gov/ohrms/dockets/default.htm (last visited May 12, 2008).

In April 2005, the FDA published a notice in the Federal Register announcing that the FDA was performing an experimental study on carbohydrate content claims on food labels. *See* Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of Carbohydrate Content Claims on Food Labels, 70 Fed. Reg. 18032 (Apr. 8, 2005). In this notice, the FDA reiterated that current FDCA regulations make no provision for the use of nutrient content claims that characterize the level of carbohydrate in foods. *Id.* at 10833. The stated purpose of the study and data collection was "to help enhance FDA's understanding of consumer response to carbohydrate content claims on food labels." *Id.* The FDA stated that it planned to test different types of carbohydrate claims, including "carb free," "low carb," and "Xg net carbs" (where "X" is a number). *Id.*

In November 2007, the FDA published in the Federal Register an advance notice of proposed rulemaking to request comment on contemplated changes to regulations concerning nutrient labeling. *See* Food Labeling: Revision of Reference Values and

Mandatory Nutrients, 72 Fed. Reg. 62149 (Nov. 2, 2007). In this notice, the FDA stated that when it issued the existing nutrient labeling regulations in 1993, "it considered the diet and health information that was current at the time," but "[n]ew information has since become available" which has "stimulated extensive discussion in the scientific community." *Id.* at 62150. With respect to carbohydrates, in particular, the FDA referenced the pending citizens' petitions concerning carbohydrate content claims, and solicited comment on "what should be included or excluded in the current calculation of 'total carbohydrate,'" and whether carbohydrates should "be classified and declared in nutrition labeling based on their chemical definition or their physiological effect."[3] *Id.* at 62168 & n. 7, 62169.

Notably, although before 2004, the FDA issued warning letters to various companies, including *amicus* Rexall Sundown, concerning the use of claims such as "low carb" and the exclusion of "non-impact" carbohydrates from the calculation of the "total carbohydrates," the FDA has not taken any other enforcement action since accepting the petitions seeking new guidelines on carbohydrate labeling and beginning its study of the carbohydrate labeling issue. At the same time, the FDA has indicated

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[3] The FDA's website shows the petitions remain "pending" as of the filing of this *amicus* brief. *See* Chronological List of Petitions, available at http://www.fda.gov/ohrms/dockets/CITPETS/04citpetlist.htm.

informally that it essentially accepts the use of "net carbohydrate" claims. In a letter to the National Consumers League, Acting FDA Commissioner Crawford wrote that "although FDA has not issued guidance regarding the use of such statements, the agency has not generally objected to the use of 'net carbohydrate' type information on food labels if the label adequately explains how the terms are used so that it would not be false or misleading to consumers."[4] Letter from Lester M. Crawford, Acting Commissioner of Food and Drugs, FDA, to Linda F. Golodner, President, National Consumers League (Nov. 19, 2004) (No. 2004p-0105), available at http://www.fda.gov/ohrms/dockets/dockets/04p0105/04p-0105-ans00001-vol1.pdf; *see also* letter from Michael M. Landa, Deputy Director for Regulatory Affairs,

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[4] While the FDA considers the carbohydrate content labeling issue, the United States Department of Agriculture ("USDA") Food Safety and Inspection Service ("FSIS") has issued interim regulatory guidance to companies under its oversight concerning the proper use of carbohydrate content claims such as "Net Carbs," "Effective Carbs," and "Net Impact Carbs." *See* FSIS, Statement of Interim Policy on Carbohydrate Labeling Statements (Dec. 22, 2003), available at http://www.fsis.usda.gov/OPPDE/larc/Policies/CarbLabel.htm. The United States Department of the Treasury's Alcohol and Tobacco Tax and Trade Bureau ("TTB") has issued similar interim guidelines concerning permissible use of claims such as "low carbohydrate," "reduced (lower) carbohydrate," and "fewer carbohydrates." *See* TTB, Rul. 2004-1, Caloric and Carbohydrate Representations in the Labeling and Advertising of Wine, Distilled Spirits and Malt Beverages (Apr. 7, 2004), available at http://www.ttb.gov/rulings/2004-1.pdf.

Center for Food Safety and Applied Nutrition, FDA, to Nancy L. Schnell, Deputy General Counsel, Unilever United States, Inc. (Sept. 15, 2005) (No. 2004p-0298), available at http://www.fda.gov/ohrms/dockets/dockets/04p0298/04p-0298-ans0001-vol2.pdf.

D. The California Supreme Court's Decision In The *Farm Raised Salmon* Case Arguably Would Permit Private Actions To Enforce Restrictions On Carbohydrate Content Claims In State Duplicates Of The FDCA, Directly Conflicting with the FDA's Considered Decision Not To Pursue Such Enforcement Actions.

As explained, the FDA has recognized in the face of changing views in nutritional science that carbohydrate content claims may be both proper and helpful to consumers concerned about maintaining healthy diets. As a consequence, the FDA has exercised its congressionally-granted authority not to take formal enforcement actions against companies distributing products bearing these carbohydrate content claims while the FDA considers revising existing regulations accordingly. *See* 21 U.S.C. § 336 (2008) (granting the FDA the power not to prosecute "minor violations of [the FDCA] whenever [it] believes that the public interest will be adequately served by a suitable written notice or warning"); *see also Heckler v. Chaney*, 470 U.S. 821, 835 (1985) (recognizing that the FDCA's "enforcement provisions . . . commit complete discretion to [the FDA] to decide how and

when they should be exercised"). This Court has observed that "[t]his flexibility [concerning enforcement] is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives." *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 (2001).

Despite the FDA's considered judgment, which this Court has recognized as vital to the accomplishment of federal objectives, the California Supreme Court's decision in the *Farm Raised Salmon* case arguably would permit private state-court actions, like the *Jarvis* case, to proceed so long as they are premised on purported violations of state-law duplicates of the FDCA, rather than the FDCA itself – even though the FDA has declined to pursue enforcement actions and is reconsidering the relevant regulations.[5]

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[5] It bears noting that the California Supreme Court was simply wrong in stating that "[n]o court, particularly after passage of the NLEA, has ever held that states may not provide a private remedy for the violation of state laws imposing requirements identical to those imposed by federal law" under the FDCA. Pet. App. 30. Both before and after passage of the NLEA, courts held precisely that. *See Animal Legal Defense Fund Boston, Inc. v. Provimi Veal Corporation*, 626 F. Supp. 278, 283 (D. Mass. 1986) (private claims seeking to enforce *both* the FDCA *and* "the Massachusetts statute which parallels the FDCA" were preempted by federal law); *Fraker v. KFC Corp.*, No. 06-CV-01284, 2007 WL 1296571, *4 (S.D. Cal. Apr. 30, 2007) ("to the extent Plaintiff contends that alleged violations of the FDCA *and [California's] Sherman Law* give rise to viable

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As the California Supreme Court observed, *state governments* may be able to prosecute under their state counterparts to the FDCA the very same purported violations concerning carbohydrate content claims that the FDA has declined to pursue pending its reconsideration of the relevant federal regulations. *See* Pet. App. 34. But the FDA has stated its intention "to work with the States to attempt to ensure that State provisions that are identical to provisions in the [FDCA] are interpreted by the States in a way that is as consistent as possible with the FDA's interpretation of the Federal provisions." 58 Fed. Reg. 2457, 2458 (Jan. 6, 1993). While the FDA has means at its disposal to prevent *state governments* from interfering with its enforcement decisions concerning carbohydrate content claims, it has no such control over private parties and their attorneys. The California Supreme Court's decision gives individuals carte blanche to override the FDA's judgment.

Other courts have recognized that it would undermine the FDA's regulatory authority to permit private parties to prosecute claims based on matters that the FDA has yet to resolve definitely. For example, in *Summit Technology, Inc. v. High-Line Medical Instruments Co., Inc.*, 922 F.Supp. 299 (C.D. Cal. 1996), the court considered a private Lanham Act claim arising from the defendants' allegedly unlawful

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[private] state law claims, such claims are impliedly preempted by the FDCA").

importation, promotion, and use of ophthalmological laser devices that were not approved by the FDA. The court noted:

> It is evident from the Complaint (and the accompanying exhibits) that the FDA is continuing to investigate whether Defendants have actually violated FDA regulations. . . . And, regardless of any warning letters that the FDA may have sent to Defendants, it is clear that the FDA has not completed this investigation. Indeed, after further review, the FDA *could* ultimately decide . . . that further approval procedures are unnecessary. Plaintiff's Lanham Act cause of action would thus "usurp[ ] the FDA's discretionary role in the application and interpretation of its regulations."

Id. at 306 (emphasis in original) (citations omitted) (quoting *Fender v. Medtronic, Inc.*, 887 F. Supp. 1326, 1332 (E.D. Cal. 1995)).[6]

Similarly, it is evident that, despite any warning letters it may have issued, the FDA is continuing to

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[6] In a subsequent order, the court reiterated: "Simply judging from the correspondence attached as exhibits to the Complaint, it is apparent that the FDA has not yet determined whether to take action against [Defendant] for its importation of [the devices]. In essence, the FDA has not yet determined how it will interpret and enforce its own regulations with regard to this question, and the Court must therefore decline to usurp the FDA's authority." *Summit Technology, Inc. v. High-Line Medical Instruments Co., Inc.*, 933 F. Supp. 918, 934 (C.D. Cal. 1996).

investigate whether carbohydrate content claims of the type at issue in *Jarvis* should be expressly permitted. A private action based on such carbohydrate content claims would usurp the FDA's discretionary role in the application and enforcement of its own regulations, regardless of whether the action is grounded in the FDCA or one of the FDCA's state equivalents.

Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc., 902 F.2d 222 (3d Cir. 1990), is also instructive. There, the Third Circuit addressed "the question whether a Lanham Act false labeling claim exists against a [cough syrup] manufacturer who lists an ingredient as 'inactive' when FDA standards seem to require that such an ingredient to be labeled as 'active.'" *Id.* at 230. Despite what FDA standards "seemed" to require, the FDA had not conclusively found that the ingredients in question had to be labeled "active." *Id.* The Third Circuit declined to recognize the Lanham Act claim, noting that such a claim would usurp the FDA's authority to interpret and enforce its own regulations. *Id.* at 231. The Third Circuit explained: "Because 'agency decisions are frequently of a discretionary nature or frequently require expertise, the agency should be given the first chance to exercise that discretion or to apply that expertise.'" *Id.* (quoting *McKart v. United States*, 395 U.S. 185, 194 (1969)).

Significantly, the Third Circuit in *Sandoz* noted that the private plaintiff was "free to petition the FDA to investigate the[ ] alleged labeling violations"

and, in fact, the plaintiff "represent[ed] that it has embarked upon this path already." *Sandoz*, 902 F.2d at 231, n. 10. But the Third Circuit stated: "The fact that [the plaintiff] has been unable to get a quick response from the FDA . . . does not create a claim . . . under the Lanham Act." *Id.*

The same principle applies to carbohydrate content claims. The propriety of such claims is the subject of several FDA petitions that the FDA is in the process of considering. The FDA's inability yet to resolve the matter demonstrates the complexity of the issue, the need for the FDA to make a decision in a considered manner based on its specialized knowledge, after evaluating all the comments it has solicited, and the mischief that will ensue if private parties could jump ahead of the FDA's deliberative process.

Put simply, it is the FDA's province, not private litigants', to interpret relevant FDCA regulations and make decisions about when and how to apply them in light of the FDA's expertise in the areas it regulates. The California Supreme Court's decision ignores this, allowing private parties, who, unlike the FDA, do not represent the public interest, to usurp the FDA's authority so long as they do so pursuant to state duplicates of the FDCA and not the FDCA itself. That is a distinction without a difference. The deleterious effect on the FDA's ability to regulate consistently

and thoughtfully in the field committed to its discretion is exactly the same.

CONCLUSION

For the foregoing reasons, *amicus* Rexall Sundown respectfully requests that the Court grant the petition for certiorari.

Respectfully submitted,

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